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NOV 12 1991

Tatsuya Ikeda
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Somerville, NJ 08876 - 1258

Re: Patent Term Extension
Application for
U.S. Patent No. 4,587,258

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,587,258 issued May 6, 1986, which claims the human drug product Altace, is eligible for patent term extension under 35 USC § 156. The period of extension has been determined to be 632 days.

The period of extension has been calculated using the FDA determination of the length of the regulatory review period published in the Federal Register of May 10, 1991. Under 35 USC § 156 (c):

$$\begin{aligned}\text{Period of Extension} &= 1/2 (\text{Testing Phase}) + \text{Approval Phase} \\ &= 1/2 (918) + 813 \\ &= 1,272 \text{ days}\end{aligned}$$

Since the regulatory review period began February 5, 1984, before the patent issue date, only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period. The period of time from the start of the regulatory review period on February 5, 1984, up to the issuance of the patent on May 6, 1986, is 820 days. This period is subtracted from the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory review period: $1738 - 820 = 918$ days. No determination of a lack of due diligence was made.

The 14 year exception of 35 USC § 156 (c) (3) operates to limit the term of extension in the present situation because it provides that the period remaining in the term of the patent measured from the date of approval of the approved product (January 28, 1991) when added to the period of extension calculated above (1,272 days) cannot exceed fourteen years. The period of extension is thus limited to January 27, 2005, by operation of 35 USC § 156 (c) (3). Since the patent term of seventeen years (35 USC § 154) would expire on May 6, 2003, the period of extension is the number of days to extend the term of the patent from this time to January 27, 2005, or 632 days.

The limitations of 35 USC § 156 (g) (6) do not operate to further reduce the period of extension determined above.

U.S. Patent No. 4,587,258

A single request for reconsideration of this final determination as to eligibility and the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136 (a) are not applicable to this time period. In the absence of such request for reconsideration, the Commissioner will issue to the applicant for extension of the term of Patent No. 4,587,258 a certificate of extension, under seal, for a period of 632 days.

Upon issuance of the certificate of extension the following information will be published in the Official Gazette:

U.S. Patent No.:	4,587,258
Granted:	May 6, 1986
Applicant:	Gold et al
Owner of Record:	Schering Corporation
Title:	ANGIOTENSIN-CONVERTING ENZYME INHIBITORS
Classification:	514/412
Product Trade Name:	Altace
Term Extended:	632 days

C. E. Van Horn

Charles E. Van Horn
Patent Policy & Programs Administrator
Office of the Assistant Commissioner for Patents

cc: Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs (HFY-20)
Food and Drug Administration
5600 Fishers Lane, Room 11-44
Rockville, MD 20857

RE: Altace
FDA Docket No.: 91E - 0136

All communications respecting this case should identify it by number and names of parties.



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BOARD OF PATENT APPEALS
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Interference No. 101,833

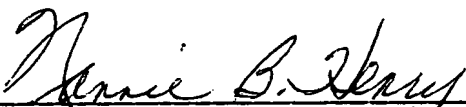
Gold, et al

v.

Teetz, et al

The copy of the agreement under 35 USC 135(c) filed by Gold, et al September 30, 1988 is acknowledged. Pursuant to their request, this agreement will be kept separate from the file of the interference as provided in the statute.

NBH:ce


Nannie B. Henry, Deputy Clerk
Board of Patent Appeals and
Interferences
703/557-4005